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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/999,752	06/04/1997	FIONA CATHERINE MILLAR	TEVNHC 3.0-200	4312

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/999,752	MILLAR, FIONA CATHERINE	
	Examiner	Art Unit	
	S. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/28/08*.

2a)☒ This action is FINAL. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-27 and 29-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *46 and 47* is/are allowed.

6)☒ Claim(s) *23-27, 29-33, 35, 36, 38-40, 43 and 45* is/are rejected.

7)☒ Claim(s) *34,37,41,42 and 44* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/09/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

Claims 23-26, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz WO 93/11747, in view of Schultz et al. US 5,899,201.

Schultz '747 teaches a suspension aerosol formulation in which the drug is in particulate form (page 5) and the fluorocarbon propellant is HFC 134a or HFC 227 (page 3). Page 5, lines 27-31 teach that the formulation does not need additional components. Page 9 teaches that ethanol can be optionally included to about 20% and the surfactant is also optional. Example 8 discloses a canister containing the pirbuterol acetate, HFC 227 and ethanol at 10% without a surfactant. Preferred drug for use in the formulation includes formoterol (page 7, 3rd paragraph).

Schultz '747 does not teach the claimed actuator.

Schultz '201 teaches an actuator for use in connection with medicinal aerosol formulations. The actuator comprises housing 13 adapted to receive and support aerosol canister containing a medicinal aerosol formulation, a metered dose valve, and an exit orifice with size from about 0.25 mm (250 µm) (abstract; and column 3, lines 5 through column 4, lines 1-21). Thus, it would have been obvious to one of ordinary skill in the art to modify the aerosol canister of Schultz '747 to include the actuator in view of the teachings of Schultz '201, because Schultz '201 teaches compared to a conventional actuator, the actuator of Schultz '201 is capable of delivering a dose of drug in the form of an aerosol such that more drug reaches the area of the lung where it is therapeutically effective,

and less drug is deposited in the mouth and throat, thus decreasing undesired systemic effects of the drug.

Claims 27, 31-33, 35, 36, 38-40, 43 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz WO 93/11747, in view of Schultz et al. US 5,899,201 and Greenleaf et al. US 5,348,730.

Schultz is relied upon for the reason stated above. Schultz does not explicitly teach salbutamol as the bronchodilator.

Greenleaf teaches bronchodilator such as epinephrine, phenylepinephrine, and salbutamol (column 5, lines 17-30). Thus, it would have been obvious to one of ordinary skill in the art to include sabutamol in the suspension formulation of Schultz, because Greenleaf teaches sabutamol is a known bronchodilator among other bronchodilators, and because Schultz teaches a suspension aerosol formulation suitable for a wide variety of bronchodilators.

Response to Arguments

Applicant's arguments filed 12/09/08 have been fully considered but they are not persuasive.

Applicant argues that the teachings of *Schultz* '201 do not fill the void of *Schultz* '747, especially in terms of the size of the orifice, so as to provide any rationale by which a person skilled in the art would have arrived at the claimed invention. *Schultz* '201 teaches improved delivery of solution or suspension

medicinal aerosol formulations by the addition of a *constriction* aperture to a *conventional* actuator. In describing exit orifices of conventional actuators, Col. 4, ii. 1-2 of *Schultz* '201 discloses that common minimum exit orifice diameters range from about 0.25 mm (250 microns) to about 0.64 mm (640 microns). In that same paragraph, *Schultz* '201 also teaches that " [w]ith conventional actuators *wider diameters* commonly are used in connection with *suspension aerosol* formulations." (Col. 4, ii. 1-4, emphasis added). *Schultz* goes on to explain that "[n]arrower diameters are used in connection with solution aerosol formulations and with suspension aerosol formulations that are particularly difficult to deliver in the form of an aerosol containing a high respirable mass." (Col. 4, ii. 5-8). Thus, when the paragraph bridging Cols. 3-4 in *Schultz* '201 is considered in its entirety, it becomes clear that a person skilled in the art would have selected an orifice diameter greater than 300 microns and well at the higher end of the 0.25 mm - 0.64 mm (250 - 640 microns) range for a suspension aerosol formulation. This view is entirely consistent with working examples in *Schultz* '201 that describe a standard suspension actuator having an exit orifice diameter of 0.56 mm (560 microns). *See Schultz* '201 Col. 6, ii. 1-4. Thus, the diameters of the orifices taught in *Schultz* '201 for delivering a suspension aerosol formulation are outside, and much greater *(e.g.,* about 2 to 5 times greater) than the range of i00 to 300 microns as recited in the independent claims. As such, *Schultz* '201 in fact teaches away from the claimed invention. To further highlight this distinction, Claim 23 recites that the bronchodilator is "substantially completely insoluble" in the propellant. In addition to this recitation, the three new

independent claims 39, 46 and 47 also recite that the aerosol formulation is a "suspension" aerosol formulation (support for which is found in bottom of page 5, for example). Thus, the present claims now clearly point out that the aerosol formulation is in the form of a suspension as opposed to a solution.

However, in response to applicant's argument that *Schultz '201 discloses that common minimum exit orifice diameters range from about 0.25 mm (250 microns) to about 0.64 mm (640 microns). In that same paragraph, Schultz '201 also teaches that " [w]ith conventional actuators wider diameters commonly are used in connection with suspension aerosol formulations*, it is noted that the use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983). Schultz is relied upon for the teaching at column 4, lines 1-2 that common minimum diameter range from about 0.25 mm, which is about 250 nm. A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989).

Accordingly, the rejections over Schultz '201 is maintained.

Claims Allowable

Claims 34, 37, 41, 42 and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 46 and 47 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1618